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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,199	07/14/2003	Karin Jarverud	P03,0232	8711

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EXAMINER	
PATEL, NATASHA	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 07/05/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/620,199	JARVERUD, KARIN	
	Examiner	Art Unit	
	Natasha N. Patel	3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *19 May 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 15-22* is/are rejected.

7)☒ Claim(s) *4-14* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 July 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The applicant's TD filed on 5/9/06 has been approved.

2. Applicant's arguments, see pgs. 2-4, filed 5/19/2006, with respect to the rejection(s) of claim(s) 1-3 and 15-22 under 35 USC § 103 have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of Notton et al. (US Patent 5,735,286).

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarverud et al. ("Analysis of the O-Wave In Acute Right Ventricular Apex Impedance Measurements With a Standard Pacing in Animals" (Med. Biol. Eng. Comput. 2002, Vol. 40, pgs. 512-519)) in view of Notton et al. (US Patent 5,735,286).

5. Regarding Claim 1, Jarverud discloses an impedance measurement unit, including an electrode arrangement (see pg. 514, 2.2, 1st sent.) for interacting with a patient to measure intracardiac impedance and to generate a corresponding impedance signal (see pg. 514, 2.2, 7th sent) in "Analysis of the O-Wave In Acute Right Ventricular Apex Impedance Measurements With a Standard Pacing in Animals" (Med. Biol. Eng.

Comput. 2002, Vol. 40, pgs. 512-519). Jarverud also discloses a notch detector connected to said impedance measurement unit which detects an occurrence of a notch in the impedance signal coincident with entry of blood into a ventricle with a portion of said impedance signal following said notch being a post-notch impedance curve (see pg. 515, 3.1, par. 2, sent. 2-4). Although Jarverud discloses only the visual detection of the notch, providing an automatic or mechanical means to replace a manual activity with accomplishes the same result is not sufficient to distinguish over prior art (*In re Venner*, 262 F.2d 91, 95, 120 USPQ 193, 194 (CCPA 1958)). Jarverud does not disclose a type of pattern recognition unit. Notton discloses a pattern recognition unit (see central digital processing unit 12; col. 3, lines 3-10), which compares the post-notch impedance curve with a stored reference impedance curve template (previous data or parameter values) to obtain a comparison result (see col. 3, lines 9-10). The examiner considers that the pattern recognition unit is capable of being used to detect an ischemic heart disease from the comparison result because it simply has to detect a change in impedance during the ventricular filling phase as taught by Jarverud (see p. 515, 4, par. 2, sent. 2-3) and a processing unit like the one described by Notton necessarily takes note of these changes during the comparison step. Furthermore, the examiner considers that Notton's comparison analysis on the entire curve automatically compares a post-notch impedance curve to the template since the whole curve includes the post-notch curve. One of ordinary skill in the art at the time of the invention would have thus found it obvious to compare the impedance curve to an impedance curve template because this is a common process in diagnostic analysis.

6. Regarding Claim 2, Notton discloses that the pattern recognition unit (see central digital processing unit 12) compares a shape (see col. 1, lines 52-53) of said post-notch impedance curve to a shape of said reference impedance curve template. The examiner considers that if the impedance signals undergo the steps of shaping and digitizing before the step of comparison, then the pattern recognition unit, which is in charge of the comparison step, must be comparing shapes of the impedance curves.

7. Regarding Claim 3, Notton discloses a differentiating unit (pre-processing unit 7) which calculates a time derivative at least of said post-notch impedance curve (see col. 2, lines 10-12), and wherein said pattern recognition unit compares a shape of said time derivative of said post-notch impedance curve with a stored reference time-derivative impedance curve template (see Figure 3B and col. 2, lines 21-22).

8. Claims 15-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jarverud et al. in view of Notton et al. (US Patent 5,735,286) as applied to Claims 1-3 above, and further in view of Noren et al. (US Patent 5,427,112).

9. Regarding Claim 15, Jarverud discloses taking the first derivative of impedance (see Figure 4b). Notton discloses a differentiating unit (pre-processing unit 7) supplied with said impedance signal for calculating a first time derivative of said impedance signal (see col. 2, lines 10-12). Notton further discloses plotting impedance values from said impedance signal relative to related values in said first time derivative to form a loop for each cardiac cycle (see Figure 6). Notton does not elaborate on the means for plotting the loop in Figure 6. Both Notton and Jarverud do not disclose a comparator for comparing the loops created by the loop generator. Noren discloses a differentiating

unit (differentiating circuit 123) supplied with an impedance signal for calculating a first time derivative of the impedance signal, a loop generator (RAM 126) connected to the impedance measurement unit and to the differentiating unit for plotting impedance values from the impedance signal relative to related values in the first time derivative to form a loop for each cardiac cycle (see col. 2, line 68-col. 3, line 8), and a comparator (comparators 1-4) connected to the loop generator for comparing the loop with a loop template to obtain a comparison result for detecting an ischemic heart disease dependent on the comparison result (see col. 10, lines 41-66). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to use the comparators described by Noren to compare the impedance loops because they are indicative of whether or not the heart is stable (see col. 11, lines 36-39), which is important to someone trying to detect an ischemic condition.

10. Regarding Claim 16, Noren discloses that the comparator compares a shape of the loop in a portion of the loop corresponding to the post-notch impedance curve, with a corresponding portion of the loop template (see col. 10, lines 55-59).

11. Regarding Claim 17, Jarverud discloses forming an average impedance signal from a plurality of impedance signals (see Figure 4a) respectively obtained during a predetermined number of cardiac cycles (see "18 sinus rhythm heart beats in sheep" in Figure 4 caption). Jarverud does not disclose a pattern recognition unit connected to an averaging unit. Notton discloses a pattern recognition unit (see central digital processing unit 12; col. 3, lines 3-10), but does not disclose an averaging unit. Noren discloses an averaging unit (floating averager 226) connected to the impedance measuring unit for

forming an average impedance signal from a plurality of impedance signals respectively obtained during a predetermined number of cardiac cycles (see col. 7, lines 21-23). Thus, it would have been obvious to one of ordinary skill in the art at the time of the invention to incorporate Noren's averaging unit into Notton's monitor to compare a post-notch impedance curve in the average impedance signal with the reference impedance curve template because Jarverud teaches the use of average impedance signals in the detection of ischemia and Noren teaches that averaging signals is simply a filtering process (see col. 4, lines 3-7) and it is well known to use filtering as a means for improving the quality of the signal, making ischemia detection easier in this case.

12. Regarding Claim 18, see rejection of similarly worded Claims 3 and 17 above.

13. Regarding Claim 19, see rejection of similarly worded Claims 3, 15, and 17 above. As to the second averaging unit, Jarverud discloses an average first derivative (see Figure 4b caption). Notten discloses (dI/dt)/I where I is the number of impedance values recorded (see col. 9, lines 40-45). The examiner considers that dividing a derivative curve by the total number of values taken is equivalent to averaging the derivative curve because both typify a set of numbers (see American Heritage Dictionary for 'average'). In addition, since Noren discloses the importance of averaging signals as a means of filtering, it would be obvious to one of ordinary skill in the art at the time of the invention to average the derivative signal similar to the averaging of the original impedance signal in order to provide clean signals that are easy to work with. In a similar manner, it would be obvious to one of ordinary skill in the art to carry out the

loop generating step and comparison analysis with the averaged signals just like they were for the original signals because the filtering offers a more accurate diagnosis.

14. Regarding Claim 20, Noren discloses an averaging unit (floating averager 126). Noren does not address the option of having two averaging units forming a single averaging unit. It would have been an obvious matter of design choice as to whether there is a single averaging unit used to average two different quantities, or two averaging units each separately used to average a single quantity. In either case, the results would be the same. Furthermore, having two averaging units would have been obvious to one of ordinary skill in the art at the time of the invention because it allows signals to be processed in parallel, eliminating the need to flip between signals and making analysis faster.

15. Regarding Claims 21 and 22, Jarverud discloses that the electrode arrangement comprises a ventricular electrode having an electrode tip and a ring (see pg. 514, 2.2, sent. 1), and wherein said impedance measuring unit measures said impedance signal between said electrode tip and said ring. Jarverud does not elaborate on whether a unipolar or bipolar electrode is used. Nor does Jarverud elaborate on a housing for the monitoring device. Notton discloses a housing for enclosing the different components of the monitor (see col. 3, lines 10-17). However, Notton does not elaborate on the type of electrode used either. The applicant does not disclose any criticality for using a unipolar electrode over a bipolar electrode or vice versa. Nevertheless, Noren discloses a similar monitor using both a unipolar and a bipolar electrode (see col. 2, lines 37-42). Thus, it would have been obvious design choice for one of ordinary skill in the art at the time of

the invention to use either the unipolar or bipolar electrode depending on the application at hand.

Allowable Subject Matter

16. Claims 4-14 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Natasha N. Patel whose telephone number is 571-272-5818. The examiner can normally be reached on M-F 8:30-5:00.

18. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

19. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NNP
6/12/06

Robert E. Pezzuto
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